

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of  
KOLTER et al.

Serial No. Not yet assigned

Filed: With application

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} BOX PCT  
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For: THE USE OF A FILM COATING AS TASTE-MASKING COATING OF  
ORAL DOSAGE FORMS

PRELIMINARY AMENDMENT

Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231  
Sir:

Prior to examination, kindly amend the above-identification as follows.

IN THE CLAIMS

3. The use of a film coating as claimed in claim 1 [either of claims 1 or 2], wherein the film-forming water-soluble polymers are selected from the group of poly(vinyl lactams), vinylpyrrolidone/vinyl acetate copolymers, polyvinyl alcohols or cellulose derivatives, as water-insoluble but highly swelling polymers crosslinked poly(vinyl lactams), cellulose or cellulose derivatives or starch derivatives and as fine-particle dusting agents highly disperse silicas, fine-particle starches, fine-particle celluloses or fine-particle salts of phosphoric acid.

4. The use of the film coating as claimed in claim 1 [any of claims 1 to 3], wherein the ratio by weight amounts to

- a) 50 to 90% polyvinyl acetate
- b) 10 to 75% hydrophilic additives
- c) 0 to 20% other conventional coating ingredients
- d) and, where appropriate, 0 to 30% of a physiologically tolerated acid.

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5. The use of the film coating as claimed in claim 1 [any of claims 1 to 4], wherein the ratio by weight of the coating material a : b is from 1 : 0.1 to 1 : 0.75.
6. The use of the film coating as claimed in claim 1 [any of claims 1 to 5], wherein the taste-masking coating comprises 5 to 25% by weight based on the total weight of the coated shaped articles.
9. An oral dosage form as claimed in claim 7 [either of claims 7 or 8], which comprises as active ingredients food supplements or additives, vitamins, minerals or trace elements or active pharmaceutical ingredients.
10. An oral dosage form as claimed in claim 1 [any of claims 7 to 9], which comprises active pharmaceutical ingredients as active ingredients.
11. An oral dosage form as claimed in claim 7 [either of claims 7 or 10], which comprises as active ingredient acetaminophen, ibuprofen, naproxen, chlorpheniramine, dextromethorphan, acetylsalicylic acid, loperamide, pseudoephedrine, diphenhydramine, famotidine, cimetidine, ranitidine, nizatidine, salts or combinations thereof.
12. A taste-masked oral dosage form obtainable by compression of at least one preparation as claimed in claim 7 [claims 7 to 11] with conventional tablet excipients.

#### REMARKS

The claims have been amended to eliminate multiple dependency and to put them in better form for U.S. filing. No new matter is included. Entry is respectfully solicited.

Respectfully submitted,

KEIL & WEINKAUF

A handwritten signature in black ink, appearing to read "H B Keil". The signature is written in a cursive, flowing style.

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CLEAN COPY OF THE CLAIMS

1. The use of a film coating consisting of
  - a) polyvinyl acetate
  - b) hydrophilic additives
  - c) other conventional coating ingredients
  - d) and, where appropriate, a physiologically tolerated acidas taste-masking coating for oral dosage forms.
2. The use of a film coating as claimed in claim 1, wherein the hydrophilic additives are selected from the group of film-forming water-soluble polymers and/or from the group of water-insoluble but swelling polymers and/or from the group of very fine-particle dusting agents.
3. The use of a film coating as claimed in claim 1, wherein the film-forming water-soluble polymers are selected from the group of poly(vinyl lactams), vinylpyrrolidone/vinyl acetate copolymers, polyvinyl alcohols or cellulose derivatives, as water-insoluble but highly swelling polymers crosslinked poly(vinyl lactams), cellulose or cellulose derivatives or starch derivatives and as fine-particle dusting agents highly disperse silicas, fine-particle starches, fine-particle celluloses or fine-particle salts of phosphoric acid.
4. The use of the film coating as claimed in claim 1, wherein the ratio by weight amounts to
  - a) 50 to 90% polyvinyl acetate
  - b) 10 to 75% hydrophilic additives

- c) 0 to 20% other conventional coating ingredients
  - d) and, where appropriate, 0 to 30% of a physiologically tolerated acid.
5. The use of the film coating as claimed in claim 1, wherein the ratio by weight of the coating material a : b is from 1 : 0.1 to 1 : 0.75.
  6. The use of the film coating as claimed in claim 1, wherein the taste-masking coating comprises 5 to 25% by weight based on the total weight of the coated shaped articles.
  7. An oral dosage form with an active ingredient-containing core and a taste-masking coating consisting of
    - a) polyvinyl acetate
    - b) hydrophilic additives
    - c) other conventional coating ingredients
    - d) and, where appropriate, a physiologically tolerated acid or base.
  8. An oral dosage form as claimed in claim 7, which comprises the following substances based on the weight of the core
    - a) 30 to 98% active ingredient
    - b) 2 to 70% binder
    - c) 0.1 to 5.0% emulsifier and, where appropriate,
    - d) 2 to 30% disintegrant
    - e) and, where appropriate, 0 to 20% of a physiologically tolerated acid or base.
  9. An oral dosage form as claimed in claim 7, which comprises as active ingredients food supplements or additives, vitamins, minerals or trace elements or active

pharmaceutical ingredients.

10. An oral dosage form as claimed in claim 7, which comprises active pharmaceutical ingredients as active ingredients.
11. An oral dosage form as claimed in claim 7, which comprises as active ingredient acetaminophen, ibuprofen, naproxen, chlorpheniramine, dextromethorphan, acetylsalicylic acid, loperamide, pseudoephedrine, diphenhydramine, famotidine, cimetidine, ranitidine, nizatidine, salts or combinations thereof.
12. A taste-masked oral dosage form obtainable by compression of at least one preparation as claimed in claim 7 with conventional tablet excipients.
13. A taste-masked oral dosage form as claimed in claim 12, wherein from 0 to 40% of a physiologically tolerated acid or base are added to the tablet mixture.
14. A process for producing a taste-masked oral dosage form comprising the steps
  - a) production of medicinal substance-containing shaped articles from active ingredient, binder, disintegrant and emulsifier,
  - b) coating of medicinal substance-containing shaped articles with the film coating as claimed in claim 1 and
  - c) compression of the coated medicinal substance with conventional tablet excipients.